products on the Commerce Control List is controlled according to the provisions in each Category.

''Technology'' ''required'' for the ''development,'' ''production,'' or ''use'' of a controlled product remains controlled even when applicable to a product controlled at a lower level.

General License GTDR, without written assurance, is available for ''technology'' that is the minimum necessary for the installation, operation, maintenance (checking), and repair of those products that are eligible for General Licenses or that are exported under a validated export license.

N.B.: This does not allow release under a general license of the repair ''technology'' controlled by 1E02.e, 1E02.f, 7E03, or 8E02.a.

N.B.: The 'minimum necessary' excludes ''development'' or ''production'' technology and permits ''use'' technology only to the extent ''required'' to ensure safe and efficient use of the product. Individual ECCNs may further restrict export of 'minimum necessary' information.

General License GTDA is available for ''technology'' that is publicly available or technology arising during or resulting from fundamental research. See section 779.3 of this subchapter for details on General License GTDA.)

2. *General Software Note.* General License GTDR, without written assurance, is available for release of software that is generally available to the public by being:

a. Sold from stock at retail selling points, without restriction,[1] by means of:

1. Over the counter transactions;

2. Mail order transactions; or

3. Telephone call transactions; and

b. Designed for installation by the user without further substantial support by the supplier.

General License GTDA is available for software that is publicly available.

N.B.; The General Software Note does not apply to exports of ''software'' controlled by other agencies of the U.S. Government (see § 770.10 of this subchapter).

BILLING CODE 1505–01–D

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 892

[Docket No. 94N–0345]

Medical Devices; Classification of Transilluminators (Diaphanoscopes or Lightscanners) for Breast Evaluation

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule to classify the transilluminator (diaphanoscope or lightscanner) for breast evaluation into class III (premarket approval). This action is necessary to require manufacturers of transilluminators to submit a premarket approval application that includes information concerning safety and effectiveness tests for the device. This action is being taken under the Federal Food, Drug, and Cosmetic Act as amended by the Medical Device Amendments of 1976 and the Safe Medical Devices Act of 1990.

EFFECTIVE DATE: August 17, 1995.

FOR FURTHER INFORMATION CONTACT: Robert A. Phillips, Center for Devices and Radiological Health (HFZ–470), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–1212.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of January 13, 1995 (60 FR 3168), FDA issued a proposed rule to classify transilluminators (diaphanoscopes or lightscanners) for breast evaluation into class III. The effect of classifying a device into class III is to require each manufacturer of the device to submit to FDA a premarket approval application that includes information concerning safety and effectiveness tests for the device. A period of 90 days was provided for interested persons to submit written comments to FDA. FDA did not receive any comments on the proposal. Accordingly, the proposed rule is being adopted without change.

Environmental Impact

The agency has determined under 21 CFR 25.24(e)(2) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

Analysis of Impacts

FDA has examined the impacts of the final rule under Executive Order 12866 and the Regulatory Flexibility Act (Pub. L. 96–354). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this final rule is consistent with the regulatory philosophy and principles identified in the Executive Order. In addition, the final rule is not a significant regulatory action as defined by the Executive Order and so is not subject to review under the Executive Order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because the agency believes only a small number of firms will be affected by this rule, the agency certifies that the final rule will not have a significant economic impact on a substantial number of small entities. Therefore, under the Regulatory Flexibility Act, no further analysis is required.

List of Subjects in 21 CFR Part 892

Medical devices, Radiation protection, X-rays.

Therefore, under the Federal Food, Drug, and Cosmetic Act, and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 892 is amended as follows:

PART 892—RADIOLOGY DEVICES

1. The authority citation for 21 CFR part 892 continues to read as follows:

Authority: Secs. 501, 510, 513, 520, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351, 360, 360c, 360e, 360j, 371).

2. New § 892.1990 is added to subpart B to read as follows:

§ 892.1990 Transilluminator for breast evaluation.

(a) *Identification*. A transilluminator, also known as a diaphanoscope or lightscanner, is an electrically powered device that uses low intensity emissions of visible light and near-infrared radiation (approximately 700–1050 nanometers (nm)), transmitted through the breast, to visualize translucent tissue for the diagnosis of cancer, other conditions, diseases, or abnormalities.

(b) *Classification*. Class III (premarket approval).

(c) *Date premarket approval (PMA) or notice of completion of a product development protocol (PDP) is required*. The effective date of the requirement for premarket approval has not been established. See § 892.3.

Dated: July 10, 1995.

Joseph A. Levitt,

Deputy Director for Regulations Policy, Center for Devices and Radiological Health.

[FR Doc. 95–17640 Filed 7–17–95; 8:45 am]

BILLING CODE 4160–01–F

[1] The phrase ''without restriction'' clarifies that software is not ''generally available to the public'' if it is to be sold only with bundled hardware generally available to the public. Software that is both bundled with hardware and ''generally available to the public'' does qualify for General License GDTR, without written assurance.

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Parts 1301 and 1306

[DEA No. 109F]

RIN 1117–AA20

Exemption of Agents and Employees; Affiliated Practitioners

AGENCY: Drug Enforcement Administration (DEA), Justice.

ACTION: Final rule.

SUMMARY: DEA amends its regulations to allow for the exemption of agents and employees of a registered individual practitioner, hospital, or institution from the requirement for individual registration when administering, dispensing, or prescribing controlled substances in the course of their official duties or business. The amendments make the exemption granted to agents and employees of a registrant more consistent with the recent regulatory changes involving Mid-Level Practitioners (MLP) and the fee exemption for practitioners employed by Federal, state and local government hospitals or other institutions. DEA is also amending, without prior notice, its regulations concerning the manner of issuance of prescriptions to make the language of that section consistent with the amended language set forth herein.

EFFECTIVE DATE: September 18, 1995.

FOR FURTHER INFORMATION CONTACT: G. Thomas Gitchel, Chief, Liaison and Policy Section, Office of Diversion Control, Drug Enforcement Administration, Washington, D.C. 20537, Telephone (202) 307–7297.

SUPPLEMENTARY INFORMATION: On June 15, 1994, DEA published a Notice of Proposed Rulemaking (NPRM) in the **Federal Register** (59 FR 30738) proposing to amend the language under 21 CFR 1301.24 regarding the circumstances under which agents or employees of a DEA registrant may administer, dispense, or prescribe controlled substances in the course of their official duties or business without being required to obtain an individual registration.

Specifically, § 1301.24(b) was proposed to be amended to allow that an individual practitioner who acts as an agent or employee of another individual practitioner, other than a mid-level practitioner (MLP), may administer and dispense (other than by prescription) controlled substances in the normal course of his/her official duties or business under the registration of the employer or principal practitioner.

Section 1301.24(c) was also proposed to be amended to allow an individual practitioner who is an agent or employee of a hospital or other institution to administer, dispense, or prescribe controlled substances under the registration of the hospital or other institution in lieu of becoming individually registered. The provisions outlined under § 1301.24 (c)(1) through (c)(6) set forth the procedures under which an individual practitioner may administer, dispense and prescribe controlled substances utilizing the hospital or other institution's registration number.

DEA received two written comments on the proposed amendments.

The first commentor questioned whether the amended regulation would continue to allow hospital or institution residents and non-private practice staff physicians, in the course of inpatient and outpatient treatment of patients, to prescribe controlled substances under that hospital or institution's DEA registration number. The specific concern was with the potential financial impact on the institution if the proposed amendments required individual registration numbers for a hospital or institution's staff.

The intent of the amendments is to expand the existing exemption from the registration requirement to include a greater population of practitioners. The language of § 1301.24(c) deletes the restriction of an individual practitioner ''who is an intern, resident, mid-level practitioner, etc.'' and replaces that language with ''[a]n individual practitioner''. The amendments will not affect the authority of those individual practitioners, i.e., interns, residents, mid-level practitioners, foreign trained physicians, etc., already authorized to dispense controlled substances under a hospital or institution registration number.

The first commentor additionally wished to ensure that prescriptions issued by agents or employees of a registered hospital or institution would be valid at community pharmacies in the event that patients choose not to use the prescribing institution's pharmacy. Prescriptions issued by agents or employees, consistent with the exemption, are legitimate prescriptions that may be filled at any local registered pharmacy. The regulations do not restrict dispensing of prescriptions to the prescribing hospital or institution.

The second commentor raised three separate concerns. The first inquired as to who has the oversight responsibility for determining whether a given agent or employee, while operating in the usual course of his/her duties, is authorized to handle controlled substances in the jurisdiction in which the registrant practices.

The responsibility for determining whether a registrant's agents and/or employees are authorized by state law to handle controlled substances lies with the registrant. As a threshold matter, DEA cannot register an applicant to handle controlled substances unless that individual practitioner, hospital or other institution has the necessary state authorization or permission to engage in such activities. DEA registration does not convey to a practitioner, hospital or institution any specific authority or permission to engage in controlled substances activities beyond such state authority. Title 21 CFR 1307.02 states ''Nothing in parts 1301–1308, 1311, 1312, or 1316 of this chapter shall be construed as authorizing or permitting any person to do any act which such person is not authorized or permitted to do under other Federal laws or obligations under international treaties, conventions or protocols, or under the law of the State in which he desires to do such act nor shall compliance with such parts be construed as compliance with other Federal or State laws unless expressly provided in such other laws.''

DEA registrants are responsible for ensuring that any controlled substance activities carried out pursuant to their DEA registrations are in full compliance with all applicable Federal and State laws governing controlled substances. Section 1301.24(c)(3) spells out the requirement that a hospital or other institution must verify that individual practitioners who will administer, dispense or prescribe controlled substances under the facility's registration, are authorized to do so under state law. If a controlled substances activity is not authorized or permitted under other Federal or State laws, then the registrant may not allow the activity to be carried out under its registration.

The second commentor also expressed concern with a perceived inconsistency in the language set forth in § 1301.24(c) introductory text and, by reference, in § 1301.24(c)(5), in that paragraph (c) introductory text permits the individual practitioner to ''administer, dispense or prescribe'' under the hospital registration, but paragraph (c)(5) requires only that the registered hospital authorize such practitioner to ''dispense or prescribe''. The technical definition of dispense, as set forth in 21 U.S.C. 802(10), includes the administration of a controlled substance; therefore, an individual

practitioner authorized to dispense a controlled substance would also be authorized to administer a controlled substance. However, in order to avoid further confusion and to maintain consistency, paragraph (c)(5) will be amended to read ''administer, dispense or prescribe.''

The second commentor additionally requested that DEA provide estimates of any financial or other impact on affected entities, including any increased risk or liability. With regard to this request, it must be noted that the provisions set forth under § 1301.24 are not mandatory. If an individual practitioner, hospital or other institution chooses to use the exemptions, however, it is that registrant's responsibility to assess any potential benefits, as well as any risks or liabilities and determine whether the advantages outweigh the disadvantages in using the exemption provisions.

DEA is also amending the language of § 1306.05(b) without prior notice, in order to make the language of that section consistent with the new language in § 1301.24(c). Section 1306.05(b) relates to the manner of issuance of prescriptions issued by persons exempted from the registration requirement under § 1301.24(c). The language is being amended by deleting the reference to ''An intern, resident, or foreign-trained physician, or physician on the staff of a Veterans Administration facility, * * *'' and inserting ''An individual practitioner * * *''

The Deputy Assistant Administrator, Office of Diversion Control, hereby certifies that this rulemaking will have no significant impact upon entities whose interests must be considered under the Regulatory Flexibility Act, 5 U.S.C. 601 et seq. This final rule expands an existing exception to the registration requirements to provide regulatory relief to a greater population of practitioners. This final rule is not a significant regulatory action and therefore has not been reviewed by the Office of Management and Budget pursuant to Executive Order 12866.

This action has been analyzed in accordance with the principles and criteria in Executive Order 12612, and it has been determined that the final rule does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

List of Subjects

21 CFR Part 1301

Administrative practice and procedure, Drug traffic control, Security measures.

21 CFR Part 1306

Drug traffic control, Prescription drugs.

For reasons set out above, 21 CFR part 1301 is amended as follows:

PART 1301—[AMENDED]

1. The authority citation for part 1301 continues to read as follows:

Authority: 21 U.S.C. 821, 822, 823, 824, 871(b), 875, 877.

2. Section 1301.24 is amended by revising paragraphs (b), (c) introductory text and (c)(5) to read as follows:

§ 1301.24 Exemption of agents and employees; affiliated practitioners.

* * * * *

(b) An individual practitioner, as defined in section 1304.02 of this chapter, who is an agent or employee of another individual practitioner (other than a mid-level practitioner) registered to dispense controlled substances may, when acting in the normal course of business or employment, administer or dispense (other than by issuance of prescription) controlled substances if and to the extent that such individual practitioner is authorized or permitted to do so by the jurisdiction in which he or she practices, under the registration of the employer or principal practitioner in lieu of being registered him/herself.

(c) An individual practitioner, as defined in § 1304.02 of this chapter, who is an agent or employee of a hospital or other institution may, when acting in the normal course of business or employment, administer, dispense, or prescribe controlled substances under the registration of the hospital or other institution which is registered in lieu of being registered him/herself, provided that:

* * * * *

(5) The hospital or other institution authorizes the individual practitioner to administer, dispense or prescribe under the hospital registration and designates a specific internal code number for each individual practitioner so authorized. The code number shall consist of numbers, letters, or a combination thereof and shall be a suffix to the institution's DEA registration number, preceded by a hyphen (e.g., AP0123456–10 or AP0123456–A12); and

* * * * *

PART 1306 [AMENDED]

1. The authority citation for part 1306 continues to read as follows:

Authority: 21 U.S.C. 821, 829, 871(b), unless otherwise noted.

2. Section 1306.05 is amended by revising paragraph (b) to read as follows:

§ 1306.05 Manner of issuance of prescriptions.

* * * * *

(b) An individual practitioner exempted from registration under § 1301.24(c) of this chapter shall include on all prescriptions issued by him or her the registration number of the hospital or other institution and the special internal code number assigned to him or her by the hospital or other institution as provided in § 1301.24(c) of this chapter, in lieu of the registration number of the practitioner required by this section. Each written prescription shall have the name of the physician stamped, typed, or handprinted on it, as well as the signature of the physician.

* * * * *

Dated: June 16, 1995.

Gene R. Haislip,

Deputy Assistant Administrator, Office of Diversion Control.

[FR Doc. 95–17515 Filed 7–17–95; 8:45 am]

BILLING CODE 4410–09–M

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

Federal Highway Administration

23 CFR Part 1204

RIN 2127–AE90

[NHTSA Docket No. 93–21; Notice 2]

Amendments to Highway Safety Program Guidelines

AGENCY: National Highway Traffic Safety Administration (NHTSA) and Federal Highway Administration (FHWA), Department of Transportation (DOT).

ACTION: Revisions to guidelines.

SUMMARY: Section 2002 of the Intermodal Surface Transportation Efficiency Act of 1991 (ISTEA), Highway Safety Programs, requires that the uniform guidelines for State Highway Safety Programs include six critical programs. This notice amends the contents of existing Part 1204 by adopting guidelines on three of these programs: Speed Control; Occupant Protection and Roadway Safety. This notice also revises six of the existing guidelines to reflect new issues and to emphasize program methodology and approaches that have proven to be successful in these program areas. Finally, this notice removes the guidelines from the Code of Federal